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EXAMINER	
FISHER, ABIGAIL L	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,811	NOGAMI, EIJI	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-12 and 14-21* is/are pending in the application.

4a) Of the above claim(s) *11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-10 and 14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Amendments/Remarks filed on May 6 2008 is acknowledged. Claims 3, 6 and 13 were/stand cancelled. Claims 1 and 7 were amended. Claims 14-21 were added. Claims 1-2, 4-5, 7-12, 14-21 are pending. Claims 11-12 are withdrawn as being directed to a non-elected invention. Claims 1-2, 4-5, 7-10 and 14-21 are directed to the elected invention.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Priority

Receipt is acknowledged of a certified copy of the priority document submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Interpretation

Claim 18 is directed to heat-sealing adhesives. The language of the claim states that the heat-sealing adhesive is one of a homopolymer of vinyl acetate and a copolymer between vinyl acetate and vinyl pyrrolidone. The examiner is interpreting

this claim as a Markush claim as this claim depends from claim 17 which states that the intermediate layer includes **a** heat-sealing adhesive. Therefore, claim 18 is interpreted as the heat-sealing adhesive being selected from the group consisting of a homopolymer of vinyl acetate and a copolymer between vinyl acetate and vinyl pyrrolidone.

Additionally, claims 14 and 15 are also interpreted as Markush claims as the language of the claims is "comprises one of". Therefore this phrase is interpreted as selected from the group consisting of.

Claim Objections

Claim 16 is objected to because of the following informalities: the examiner believes that parastalsis is incorrectly spelt and should correctly be spelt as peristalsis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is a new matter rejection.

Claim 16 claims that the gel-forming layer comprises a parastalsis (peristalsis) promoting agent. The applicant has indicated that support for this limitation can be found on page 26, lines 8-14. However, the examiner can not find this support. The instant specification does not contain the word parastalsis or peristalsis. The specification at page 26, lines 8-14 is directed to a form of the instant invention composition which form a gel having a size, shape, elasticity, viscosity and so on that make swallowing easy. However, this section does not indicate what a parastalsis promoting agent is nor species that would meet this particular limitation. Consequently, the instant specification does not provide support for the limitation that the gel-forming layer comprises a parastalsis promoting agent.

The following claim is additionally rejected under 35 U.S.C 112, first paragraph for the following reason.

Claim 16 is directed to encompass parastalsis promoting agents, which only corresponds in some undefined way to specifically instantly disclosed chemicals. None of these agents meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. **Note:**

MPEP 2163.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

The skilled artisan cannot envision the detailed chemical structure of the encompassed agents regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Circ. 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, (Fed. Cir. 1991). In Fiddes v. Baird, 30 USPQ2d 1481, 1483, (Bd. Pat. App. & Int. 1993), claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc.,

that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "**sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure**." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003). Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-5 are depending from claim 3, which has been cancelled. Therefore, it is unclear how a claim can depend from a cancelled claim. In the interest of furthering prosecution, claim 4 will be interpreted as depending from claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-5, 7-10 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamura et al. (US Patent No. 5914118).

Applicant Claims

Applicant claims an orally administered agent comprising an edible polymer layer containing a drug; a first water-swellable gel forming layer on one side of the drug-containing layer and a second water-swellable gel-forming layer provide don the other side of the drug-containing layer wherein the first water-swellable layer and second water-swellable alyer contain a water-swellable gel-forming agent and a film-forming agent. The amount of water-swellable gel-forming agent in the first water-swellable gel forming layer or second layer is 15 to 70 wt% and the content of the film-forming agent in the first water-swellable gel-forming layer or second layer is 30 to 85%.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Yamamura et al. is directed to a multi-layered film preparation having a drug-containing layer which contains a base material and a difficult to dissolve in water layer and a powdery adhesive compound layer (abstract). Examples of the water-soluble high molecular weight substance to be utilized as the main base material include cellulose derivative such as hydroxypropylcellulose (HPC) as well as polymer such as polyvinyl alcohol. These agents may be utilized solely or in combination thereof. It is taught that these agents are excellent in formability of a softy film especially HPC (column 2, lines 51-61). Most if not all of the examples utilize HPC in every layer of the multi-layered device. Agents for making the layer difficult to dissolve include ethylcellulose, shellac, etc. (columns 2-3, lines 62-67 and 1-4). Adhesive substance include carboxyvinyl polymer and its pharmaceutically acceptable non-toxic salts. These compound provided excellent adhesion when such a substance was applied on the drug containing layer (column 3, lines 5-17). Example 1 is directed to a triple-layered film preparation. The drug containing layer comprises HPC, polyethylene glycol (PEG) and the drug. The layer difficult to dissolve in water comprises HPC, PEG, and shellac. The adhesive layer comprises carboxyvinyl polymer, PEG, and HPC. This correlates to a water-swellable polymer of 25% and film forming agent of 49% for the difficult to dissolve in water layer. A water-swellable polymer of 78% and film-forming agent in 22% for the adhesive layer. The amount of edible polymer, HPC, in the drug contain gin layer is 89%. It is taught that after each layer is formed the composition is dried (examples).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Yamamura et al. do not specify that the adhesive agent can be present in both the difficult to dissolve layer as well as the adhesive layer. Yamamura et al. do not specify particular percentages or range of percentages wherein the water-swellable gel forming layer is from 15 to 70% for both outside layers as well as the film forming agent is present from 30 to 85 wt. % for both outside layers. Yamamura et al. does not exemplify a formulation comprising polyvinyl alcohol.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to utilize polyvinyl alcohol in the invention of Yamamura et al. One of ordinary skill in the art would have been motivated to either replace the HPC with polyvinyl alcohol or alternatively add polyvinyl alcohol in combination with HPC. One of ordinary skill in the art would have been motivated to utilize both HPC and polyvinyl alcohol as Yamamura et al. teach that both are suitable for the base material and that combinations can be utilized. One of ordinary skill in the art would have been motivated to replace HPC with polyvinyl alcohol as both are taught by Yamamura et al. as functional equivalents.

It would have been obvious to one of ordinary skill in the art to utilize carboxyvinyl polymer in both layers surround the drug containing layer. One of ordinary skill in the art would have been motivated to add this adhesive agent as it is taught by Yamamura et al. as providing excellent adhesion when applied to the drug-containing layer. By having the adhesive component in both layers, adhesion to the drug-containing layer can be achieved.

It would have been obvious to one of ordinary skill in the art to vary the amount of polymers in the multi-layered formulation. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takayanagi et al. (US Patent No. 4765983) in view of Kuroya et al. (US Patent NO. 5137729) and Geoghegan et al. (US Patent No. 6641839).

Applicant Claims

Applicant claims an orally administered agent comprising a plurality of drug-containing layers and a water swellable gel-forming layer wherein the drug-containing layers are heat sealed via a layer comprising a heat-sealing adhesive.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Takayanagi et al. are directed for medical tapes for oral mucosa. The tapes comprise a support layer composed of an intestine soluble polymer a medicament containing layer (abstract). The medicament layer comprises polymers capable of dissolving in the oral cavity or stomach. Specific examples include polyvinyl pyrrolidone, hydroxypropyl cellulose, polyacrylate (column 2, lines 57-68). It is taught that the medicament layer can be a component of one layer but preferably composed of two or more layers (column 3, lines 18-19). It is taught that two or more medicaments may be used simultaneously and when the medicament layer is composed of multiple layers each layer may contain different medicaments (column 3, liens 34-37). The intestine soluble polymers include hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, shellac, etc. (column 3, lines 42-49). It is taught that in the synthesis of these tapes that the composition is dried (examples).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Takayanagi et al. do not specify that the medicament layers comprise polyvinyl acetate. Takayanagi et al. do not specify that the compositions are dried with heat. However, these deficiencies are cured by Kuroya et al. and Geoghegan et al.

Kuroya et al. are directed drug preparations applicable to oral mucosa. The soft adhesive film containing the drug comprises a vinyl acetate homopolymer, an acrylic acid polymer, and a cellulose derivative (column 2, lines 50-54). It is taught that films that comprises only the vinyl acetate and acrylic acid are inferior in shape retention. A film comprised only of the acrylic acid polymer and the cellulose derivative does not withstand long-term use in the oral cavity. A film of only the vinyl acetate and cellulose

derivative hardly forms a soft film. Therefore, a film comprised of all three forms a substantially better film (column 3, lines 14-30).

Geoghegan et al. is directed to pharmaceutical formulations. It is taught that after coating, the product is transferred to a tray drying oven for drying at 50 °C.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Takayanagi et al., Kuroya et al, and Geoghegan et al. and utilize polyvinyl acetate in the medicament layers of Takayanagi et al. One of ordinary skill in the art would have been motivated to further add polyvinyl acetate as Takayanagi et al. teach that the medicament layer comprises polymers such as polyacrylates and cellulose derivatives and Kuroya et al. teach that in preparations applicable to oral mucosa that films comprises poly vinyl acetate, acrylic acid, and cellulose derivatives provide for a film with better shape retention and long-term use in the oral cavity.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Takayanagi et al., Kuroya et al, and Geoghegan et al. and utilize a drying oven to dry the resulting film. One of ordinary skill in the art would have been motivated to utilize a drying oven as Takayanagi et al. teach that the films are dried after formation and Geoghegan et al. teach that conventional drying techniques include a drying oven which is heated to a temperature of 50 °C.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-5, 7, 8-10 and 14-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 11540952. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims an orally administered agent comprising an edible polymer layer containing a drug; a first water-swellable gel forming layer on one side of

the drug-containing layer and a second water-swellable gel-forming layer provide don the other side of the drug-containing layer wherein the first water-swellable layer and second water-swellable alyer contain a water-swellable gel-forming agent and a film-forming agent. The amount of water-swellable gel-forming agent in the first water-swellable gel forming layer or second layer is 15 to 70 wt% and the content of the film-forming agent in the first water-swellable gel-forming layer or second layer is 30 to 85%.

Copending '952 claims an orally administered pharmaceutical composition comprising a first water-swellable gel-forming layer, a second water-swellable gel-forming layer. These layers enclose a drug-containing layer.

Copending '952 does not claim particular polymers utilized in the water-swellable gel forming layers or the drug-containing layer. Copending '952 does not claim particular amounts of polymers utilized in the layers.

Therefore, the relationship between the instant application and copending '952 is a genus-species relationship. Carboxyvinyl polymer is a particular type of water-swellable gel-forming agent.

Regarding the claimed amounts of polymer, it would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

Therefore, both the instant application and copending '952 are directed to similar subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 17-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10592953. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims an orally administered agent comprising a plurality of drug-containing layers and a water swellable gel-forming layer wherein the drug-containing layers are heat sealed via a layer comprising a heat-sealing adhesive.

Copending '953 is directed to a method for producing a pharmaceutical composition comprising a first functional layer provided to one side of a drug-containing layer and a second functional layer layer. The drug containing layer comprises a thermoplastic polymer as a base. As claimed there can be multiple intermediate drug containing layers. The functional layers are formed from water-swellable gel-forming layers. The thermoplastic edible polymers include polyvinylpyrrolidone, vinylpyrrolidone-vinyl acetate copolymer and polyvinyl acetate.

Copending '953 is directed to the method of producing a pharmaceutical composition. The pharmaceutical composition produced is the same as that instantly

claimed. Therefore, both the instant application and copending '953 are directed to similar subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616